HFI-35 9/9/97 661

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 21 1997

WARNING LETTER

Ref:OC:I1-1759

via FEDERAL EXPRESS

Mr. James M. Nevels
Audio-Visual Specialist
Player's Casino
507 N. Lakeshore Drive
Lake Charles, Louisiana 70601

Dear Mr. Nevels:

This letter is written to advise you of items of noncompliance with the Federal laser product performance standard and conditions of your laser light show variance, Number 95V-0296, encountered during the Food and Drug Administration inspection of your facility and laser light show by Mr. Dennis Butcher on March 4-5, 1997.

1. 21 CFR 1040.10(f)(2). The top cover of the projector failed to have either a redundant or fail-safe safety interlock as required.

2. 21 CFR 1040.10(f)(3). The laser light show and projector did not have a readily available remote interlock connector. There was a connector labeled "Remote Interlock", however there was a cable connected to it of unknown function and thus made the connector no longer readily available for use in an external interlock or emergency stop circuit.

3. 21 CFR 1040.10(g)(5). There were no aperture labels located close to the apertures of the northwest scanner assembly nor the collimator turret assembly.

4. 21 CFR 1040.11(c) and Variance No. 95V-0296 Condition 8(b). The laser light show is Class IV and the operator cannot view the beam path of the beam from the laser "cannon" assembly beyond the adjacent parking garage and thus cannot act to prevent illumination of aircraft that might fly into the beam.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. The production or performance of a laser light show is considered to be an act of manufacturing. This section also prohibits any manufacturer from failure to establish and maintain required records or to

submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA.

You are not being requested to submit a formal corrective action plan at this time, however, all of your equipment and future performances must comply with the Federal performance standard/variance. Persons failing to correct violations may be subject to regulatory action. If you feel that the alleged failures to comply do not exist, you may present your views and evidence within 15 days of receipt of this letter.

You must respond to each of the items listed above stating what actions you will take and what changes you will make to your equipment or shows to achieve full compliance. Your response should be submitted as a supplement to your report within 15 days of receipt of this letter, clearly referencing the appropriate accession number.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a **copy** of your response to: Director, Compliance Branch, New Orleans District Office, Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122. If you have further questions regarding these requirements, please contact Dale Smith of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Larry D. Pearson for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health